

Remarks

Claims 1-17, 25-34, and 36-47 are pending in this application. The amendments made herein to the claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the instant specification. Applicants have amended Claims 1, 15, 32 and 38.

Claim Rejections under 35 USC 103

In the Office Action, the Examiner has rejected claims 1-17, 25-34 and 36-47 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent 3,073,306 to Linder (hereinafter "Linder") or U.S. Patent 5,873,856 to Hjertman et al. (hereinafter "Hjertman") or U.S. Patent 4,373,526 to Kling (hereinafter "Kling") in view of Japanese Publication 2000-37456 (hereinafter "TERUMO") or WO 99/34850 (hereinafter "FIDERM"). Additionally, the Examiner has cited extrinsic evidence to define the term "proximate" as "*very near or next, as in space, time or order*". As a result, applicants have amended the claims to further refine the term proximate to include a specific location of the limiter.

Regardless, applicant respectfully submits that the shortcomings of Linder, Hjertman, and Kling individually are not overcome by the teachings or suggestions of combinations or modifications of the three cited references. Furthermore, the Examiner turns to TERUMO or FIDERM for proposed modifications and/or combinations of Linder, Hjertman, TERUMO, FIDERM and Kling to render the Applicant's invention obvious. Applicant contends Linder, Hjertman, and Kling teach an injection device having a movable limiter, movable just prior to the injection cycle that controls the depth of injection of the needle to the screw-adjustable (Linder) or subcutaneous (Hjertman and Kling) or intramuscular (Kling) areas of the skin. Adjustable and slid able relationship between the limiter of these references and the devices of these references differentiate them from the Applicant's claimed invention. In combinations of these references, the resultant device does not allow for precise setting of a preselected injection depth. The limiter design of the invention facilitates utilizing a needle that has an overall length that is much greater than the effective length of the needle which penetrates the skin (*i.e.*, the

exposed needle length) which is set at the time of manufacture. With a needle assembly designed in accordance with the invention manufacturing is enhanced because larger length needles can be handled during the manufacturing and assembly processes while still obtaining the advantages of having a short needle with precise injection length control for purposes of completing an intradermal injection. Furthermore, Applicant contends TERUMO and FIDERM teach injection devices having a different target area (subcutaneous) and do not provide for repeatable delivery to the intradermal portion of the skin. Applicant respectfully submits that such teachings do not render the present claims of the present application obvious. Applicant's invention is directed to an intradermal delivery device for making intradermal injections that comprises, *inter alia*, a non-movable limiter which is set at the time of manufacture and that limits penetration of the needle to the dermis layer of the skin. Design of the claimed needle assemblies having the needle's forward end extending within the claimed range ensures an intradermal injection because the needle is unable to penetrate any further than the dermal layer. In contrast, the longer needle lengths allegedly disclosed in combinations of the cited references would allow penetration of the needle to the subcutaneous layer thereby contravening the recitation in the independent claims that penetration of the needle be limited to intradermal injections.

For any of these reasons, the aforementioned feature of independent claims 1, 15, 32 and 38 cannot reasonable be said to be present in the asserted combination. The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103. Section 2143.03 of the MPEP requires the “consideration” of every claim feature in an obviousness determination. To render claims 1, 15, 32 and 38 unpatentable, however, the Office must do more than merely “consider” each and every feature for this claim. Instead, the asserted combination of the patents to Linder, Hjertman, TERUMO, FIDERM and Kling s must also teach or suggest *each and every claim feature*. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *See In re*

Wada and Murphy, Appeal 2007-3733, citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between the *claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, Applicant submits that this is why Section 904 of the MPEP instructs Examiners to conduct an art search that covers “the invention as *described and claimed*.” (emphasis added). Lastly, Applicant respectfully directs attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int'l v. Teleflex Inc.* stated that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Furthermore, consistent with the principles enunciated in *KSR*, the Patent Office’s examination guidelines for determining obviousness specify that after resolution of the *Graham* factual inquiries, the Office personnel must articulate the reasons **why** the claimed invention would have been obvious, and **mere conclusory statements are insufficient** to support an obviousness rejection. Notice entitled “Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*” 72 Fed. Reg. 57526, 57528, 57529 (October 10, 2007).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. See *In re Wada and Murphy*, citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Conclusion

In view of the Amendments submitted, and the Remarks above, Applicant respectfully submits that Claims 1-17, 25-34, and 36-47 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider his rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, Extension of Time, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

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